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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 097164,293 | 10/01/98 | GREENSPAN | 028870-131 |

HM42/1001

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EXAMINER

WEBBER, P

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

10/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Attachment

Application No. 097164,293, PTO 1404, 10/01/98

Office of Patent and Trademark

Office of Patent and Trademark

In Reply, Please Refer to

Notice of Appeal

OF

Office Action Summary

Application No.

09/164,293

Applicant(s)

Greenspan et al.

Examiner

Diana W. Webb

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 03-26-99 (Amendment C & Terminal Disclaimer)
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 12-13 and 18-26 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 12-13 and 18-26 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s): _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Claims 12-13 and 18-26 are pending in this application and considered below.

Claims 1-11 and 14-17 have been canceled.

Receipt of the applicants' amendment (Paper no. 9, received March 26, 1999) is acknowledged.

Previous rejections not repeated herein are withdrawn.

With regard to the rejection of claims 12-13 and 21, under 35 USC 103 over TORA and Guo et al., the Applicants urge that neither reference teaches the release of ions into a wound or burn. Said rejection has not been repeated. The following new ground or rejection is applied to the present claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-13, 18, 21 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meiss (US pat. #5,000,746) in view of Low et al. (US pat#4,851,046), Coleman et al. (91023289 Medline) and Wood (Medline #93159543).

Meiss teaches a wound covering for burns comprising a mat, web or fabric, provided with a layer of bioglass treated with an antibiotic substance. Column 2, lines 54-

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56; column 3, lines 19-24. Meiss further discloses that gauze compresses or synthetic materials (formed into sheets or mats), for application to wounds, already exist. Column 1, lines 15-33: claims 11-12 and 15-17.

The claims differ in requiring the composition to release ions upon contacting a wound. Low et al teach bioactive glass compositions, suitable for repair of bony periodontal material, which comprise Ca and P, wherein Ca and P migrate from the glass upon bonding to the bone (note that it is considered by the Examiner that such may be vascularized). Although Low et al deal with bone, it is considered by the Examiner that vascularized bone can be treated as a wound. Vascularized bone would be expected to behave similarly to skin wounds. Note the showing of Coleman et al that vascularized bone and soft tissue are treated the same way when tissue transfer is used for restoration. It would have been within the skill in this art area for the routineer to choose an appropriate drug (that suitable for skin treatment) which prevents and/or treats infection, *which is within the scope of the Meiss teachings (claim 15)*. See, additionally, the specification at page 2, second paragraph. With regard to the specific release of sodium into a wound, Wood teaches that a sodium chloride impregnated dressing, after three weeks of therapy, results in dramatic improvements in wound size, odor, amount and type or drainage, skin condition and appearance or the wound bed.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the Meiss wound covering product to allow release of ions, per Wood, (from the bioactive glass containing product) into the wound, per Low et al, which shows ion migration from the glass upon bonding to a bone wound. A person of ordinary skill in the art would have been motivated to make this

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modification for the purpose of ion release into a wound, for the advantages taught by Wood.

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meiss in view of Low et al., Coleman et al and Wood as applied to claims 12-13, 18, 21 and 24-26 above, and further in view of Theilmann (CA112:240557) and Freed (CA119:195701).

Meiss and Low et al are applied as above. The claims differ in the inclusion of a pharmaceutically acceptable carrier. It would have been *prima facie* obvious to modify the wound dressings of Meiss and Low et al to include a carrier. A person of ordinary skill in the art would have been motivated to include a carrier in the prior art wound dressings because Theilemann shows that synthetic bandages which contain antibiotic(s) also contain water as a carrier (i.e. the cellulose or wadding is saturated with water or an aqueous solution, such as an antibiotic - note the last two lines of the abstract) and because Freed show that wound healing compositions comprising antibiotics and injectable glass oxide beads can be administered as gels.

Further, note that the instant specification states that the glass and antibiotic combination "can be combined in any pharmaceutically acceptable carrier to facilitate application to the wound."

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meiss in view of Low et al., Coleman et al and Wood as applied to claim 12-13, 18, 21 and 24-26 above, and further in view of Loeffler et al, (CA127:140572).

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Meiss and Low et al are applied as above. The claims differ in requiring a multichamber apparatus or syringe, with mixing means. It would have been prima facie obvious to a person of ordinary skill in the art to use a multibarrel injection means with mixing means to deliver the wound sealant. A person of ordinary skill in the art would have been motivated to employ injection means, including that of Meiss, to deliver antibiotic formulations because Loeffler et al show the conventionality of topical injection of such formulations (i.e. topical wound healing promoters) to be a matter of routine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela S. Webber whose telephone number is (703) 308-4427. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

psw *psw*

July 2, 1999/August 6, 1999

August 13, 1999/August 16, 1999

September 21, 1999/September 29, 1999

Donald E. Adams
DONALD E. ADAMS
SUPERVISORY PATENT EXAMINER